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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,601	12/03/2003	Gudmundur Fertram Sigurjonsson	SIGU3012/JEK/JJC	4601

23364 7590 09/05/2007
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EXAMINER

LEWIS, KIANDRA CHARLE

ART UNIT	PAPER NUMBER
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3772

MAIL DATE	DELIVERY MODE
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09/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/725,601

Applicant(s)

SIGURJONSSON ET AL.

Examiner

Kiandra C. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7-10,12,15,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7-10,12,15,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Allowable Subject Matter

The indicated allowability of claims 1-3,5,7-10,12,15,19 and 20 is withdrawn in view of the newly discovered reference(s) to Cartmell et al US 5,489,262: Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims rejected 1, 2, 5 and 7 are under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. 5,160,328; Rawlings et al. 4,657,006; Lindqvist et al. 6,051,747; Kydonieus et al. 5,591,820 and Cartmell et al. US 5,489,262.

As to claims 1, 5, and 7, Cartmell et al. ('328) disclose a wound dressing having proximal and distal sides (Fig. 2), comprising an absorbent core having proximal and distal surfaces including central and border portions; a discrete skin adherent facing layer (16 or 17) the facing layer having a proximal surfaced and a distal Surface directly secured to the absorbent core (14), said facing layer defining a region having a plurality of through extending apertures (col. 5, lines 39-41) arranged in a pattern; and a discrete pressure sensitive adhesive (20) layer applied directly to the facing layer on at least a

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segment of the proximal surface therefor only surrounding the region of the apertures (col. 4, lines 3-6, lines 11-21) wherein the facing layer and the adhesive layer are contiguous and combine to define the entirety of the proximal sides of the dressing (col. 4, lines 19-23). Cartmell et al. ('328) do not expressly disclose that the facing layer is a cross-linked silicone gel.

Rawlings et al. disclose a wound dressing containing an intermediate layer that is perforated. Rawlings et al. further teach that the intermediate layer is preferably a non-woven fabric that is formed from hydrophobic polymers. Cartmell et al. and Rawlings et al. are analogous because they are from the same field of endeavor of providing a patient with an absorbent dressing for a wound. It is known in the art that cross-linked silicone gel has hydrophobic properties, therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use a hydrophobic material as the facing layer in the invention of Cartmell et al. as taught by Rawlings et al. for the purpose of providing the additional support to the wound dressing. Rawlings et al. has not specifically stated "cross linked silicone gel", however the applicant has disclosed in the written description that the material used in the dressing is preferably hydrophobic.

In regards to cross-linked silicone gel being known in the art of wound dressings as having hydrophobic properties, Lindqvist et al. teach that the use of a hydrophobic cross-linked silicone gel in wound dressing (Fig. 1A, col. 1, lines 63-65). Lindqvist et al. further teach the need for a hydrophobic layer such as a cross-linked silicone gel in a dressing for the purpose of preventing spontaneous reflux of absorbed fluid to the skin or the wound. Lindqvist et al. also teach that it is possible to use other hydrophobic gels

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in wound dressings such as hydrophobic polyurethane gels. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use a cross-linked silicone gel as the facing layer in the invention of Carmell et al and Rawlings et al. as taught by Lindqvist et al. for the purpose of using a hydrophobic layer in a wound dressing to prevent spontaneous reflux of the absorbed fluid.

As to the adhesive layer having greater skin adherence properties than the elastomeric gel of the facing layer this limitations is inherent. Elastomeric gels (e.g. silicone gels) having low tack properties is an additional characteristic of wound dressing materials that is known in the art. Kydoneius et al. teach that commonly used pressure sensitive adhesives are known to have strong adherence to the skin ('820, col. 1, lines 22-45) and that hydrocolloid (gel forming) adhesives tend to have lower tack properties than other adhesives (col. 2, lines 8-14). It would have been obvious to one having ordinary skill in the art at the time of the invention for the adhesive layer of Carmell et al., Rawlings et al., and Lidqvist et al. to have greater skin adherence properties than the elastomeric gel as taught by Kydoneius et al. for the purpose of effectively adhering to the patient's skin.

Cartmell et al. ('262), teaches a wound dressing having border portions (fig. 4), and shows the adhesive (24) to be located along at least one segment of a border portion of the facing layer, corresponding to the border portion of the absorbent core (42). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to include adhesive on at least this segment of the wound dressing of Carmell et al., Rawlings et al., Lidqvist et al. and Kydoneius et al. as taught by

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Cartmell et al. ('262) for the purpose of adhering the dressing to skin in a manner that allows the dressing to still have good absorption capabilities

As to claim 2, the above combination teaches the plurality of apertures of the facing layer ('328, 16,17) to be located along a central portion (col. 5, lines 39-42)

As to claim 10, the above combination teaches the use of acrylate glue as an adhesive in wound dressings ('747, col. 3, lines 39-45).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. 5,160,328; Rawlings et al. 4,657,006; Lindqvist et al. 6,051,747; Kydonieus et al. 5,591,820 and Cartmell et al. US 5,489,262 as applied to claim 1 above, and further in view of Levin US 2003/0199800.

As to claim 3, Cartmell et al. ('328 & '262), Rawlings et al., Lindqvist et al. and Kydoneieus et al. disclose the limitations of the base claim but do not expressly disclose that the border portion of the facing layer generally corresponding to the border portion of the absorbent core is substantially free of apertures. Levin however teaches that the border portion of the facing layer generally corresponding to the border portion of the absorbent core is substantially free of said apertures (see figure 2). Therefore at the time of the invention it would have been obvious to one having ordinary skill in the art to modify the above combination by the limitation taught in Levin for the purpose of providing an attachment means such as an adhesive surface that is substantially leak free.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. 5,160,328; Rawlings et al. 4,657,006; Lindqvist et al. 6,051,747; Kydonieus et al. 5,591,820 and Cartmell et al. US 5,489,262 as applied to claim 1 above, and further in view of Reed et al. US 5,653,699.

As to claims 8 and 9, the above combination substantially discloses the limitations of the base claim but do not expressly state that the adhesive layer is apertured or that the apertures are only at a central portion of the facing layer. Reed et al. teaches that the pressure sensitive adhesive layer of wound dressings may be continuous or discontinuous ('699,abstract). It would have been obvious to one having ordinary skill in the art at the time of the invention to make the pressure sensitive adhesive apertured for the purpose of regulating exudates absorbed ('699, col. 13, lines 45-55).

Claim 12, 15, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. 5,160,328; Rawlings et al. 4,657,006; Lindqvist et al. 6,051,747; Kydonieus et al. 5,591,820, and Cartmell et al. US 5,489,262 and further in view of Reed et al. US 5,653,699.

As to claims 12 and 15, Cartmell et al. ('328) disclose a wound dressing having proximal and distal sides (Fig. 2), comprising an absorbent core having proximal and distal surfaces including central and border portions; a discrete skin adherent facing layer (16 or 17) the facing layer having a proximal surfaced and a distal Surface directly

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secured to the absorbent core (14), said facing layer defining a region having a plurality of through extending apertures (col. 5, lines 39-41) arranged in a pattern, and a discrete pressure sensitive adhesive (20) layer applied directly to the facing layer on at least a segment of the proximal surface therefor only surrounding the region of the apertures (col. 4, lines 3-6, lines 11-21) wherein the facing layer and the adhesive layer are contiguous and combine to define the entirety of the proximal sides of the dressing (col. 4, lines 19-23). Cartmell et al. ('328) do not expressly disclose that the facing layer is a cross-linked silicone gel.

Rawlings et al. disclose a wound dressing containing in intermediate that is perforated. Rawlings et al. further teach that intermediate layer is preferably a non-woven fabric that is formed from hydrophobic polymers. Cartmell et al. and Rawlings et al. are analogous because they are from the same field of endeavor of providing a patient with an absorbent dressing for a wound. It is known in the art that cross-linked silicone gel has hydrophobic properties, therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use a hydrophobic material as the facing layer in the invention of Cartmell et al. as taught by Rawlings et al. for the purpose of providing the additional support to the wound dressing. Rawlings et al. has not specifically stated "cross linked silicone gel", however the applicant has disclosed in the written description that the material used in the dressing is preferably hydrophobic.

In regards to cross-linked silicone gel being known in the art of wound dressings as having hydrophobic properties, Lindqvist et al. teach that the use of a hydrophobic cross-linked silicone gel in wound dressing (Fig. 1A, col. 1, lines 63-65). Lindqvist et al.

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further teach the need for a hydrophobic layer such as a cross-linked silicone gel in a dressing for the purpose of preventing spontaneous reflux of absorbed fluid to the skin or the wound. Lindqvist et al. also teach that it is possible to use other hydrophobic gels in wound dressings such as hydrophobic polyurethane gels. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use a cross-linked silicone gel as the facing layer in the invention of Carmell et al. and Rawlings et al. as taught by Lindqvist et al. for the purpose of using a hydrophobic layer in a wound dressing to prevent spontaneous reflux of the absorbed fluid.

As to the adhesive layer having greater skin adherence properties than the elastomeric gel of the facing layer this limitation is inherent. Elastomeric gels (e.g. silicone gels) having low tack properties is an additional characteristic of wound dressing materials that is known in the art. Kydoneus et al. teach that commonly used pressure sensitive adhesives are known to have strong adherence to the skin ('820, col. 1, lines 22-45) and that hydrocolloid (gel forming) adhesives tend to have lower tack properties than other adhesives (col. 2, lines 8-14). It would have been obvious to one having ordinary skill in the art at the time of the invention for the adhesive layer of Carmell et al., Rawlings et al., and Lindqvist et al. to have greater skin adherence properties than the elastomeric gel as taught by Kydoneus et al. for the purpose of effectively adhering to the patient's skin.

Cartmell et al. ('262), teaches a wound dressing having border portions (fig. 4), and shows the adhesive (24) to be located along at least one segment of a border portion of the facing layer, corresponding to the border portion of the absorbent core

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(42). Therefore it would have been obvious to include adhesive on at least this segment of the wound dressing for the purpose of adhering the dressing to skin in a manner that allows the dressing to still have good absorption capabilities. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to include adhesive on at least this segment of the wound dressing of Carmell et al., Rawlings et al., Lindqvist et al. and Kydoneius et al. as taught by Cartmell et al. ('262) for the purpose of adhering the dressing to skin in a manner that allows the dressing to still have good absorption capabilities.

Reed et al. teaches that the pressure sensitive adhesive layer of wound dressings may be continuous or discontinuous ('699,abstract). It would have been obvious to one having ordinary skill in the art at the time of the invention to make the pressure sensitive adhesive of Cartmell et al., Rawlings et al., Lindqvist et al., Kydoneius et al., and Cartmell et al. ('262) apertured as taught by Reed et al. for the purpose of regulating exudates absorbed ('699, col. 13, lines 45-55).

As to claims 19 and 20, the proximal and distal surfaces of the facing layer are generally planer ('328, fig. 2).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kiandra C. Lewis whose telephone number is 571-272-7517. The examiner can normally be reached on Mon-Thurs 9AM-6PM and alternating Fridays 9AM-5PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCL


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9/3/07